

K030380

MAR 03 2003

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	February 3, 2003
Submitter:	TissueLink Medical Inc.
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	Roberta L. Thompson Vice President, Clinical, Regulatory and Quality
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Device Information:

Trade Name:	TissueLink Sealing Forceps
Common Name:	Electrosurgery Bipolar Forceps
Classification Name:	Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the TissueLink Sealing Forceps device is made to:

TissueLink Bipolar Forceps



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 03 2003

TissueLink Medical, Inc.
Vicki S. Anastasi
Director, Regulatory Affairs
One Washington Center, Suite 400
Dover, New Hampshire 03820

Re: K030380

Trade/Device Name: TissueLink Sealing Forceps, Model I 21-202-1
Regulation Number: 878.4400
Regulation Name: Electrosurgical device cutting and coagulation and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 3, 2003
Received: February 5, 2003

Dear Ms. Anastasi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

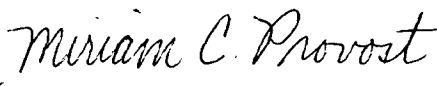
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Statement

Page 1 of 1

510(k) Number (if ~~known~~): K030380

Device Name: TissueLink Sealing Forceps device

Indications for Use:

The TissueLink Sealing Forceps (Bipolar Forceps) is a sterile, single use bipolar electrosurgical device intended to be used in general and thoracic electrosurgical applications for coagulating, sealing and transecting tissue. It is intended for, but not limited to abdominal and thoracic surgery, laparoscopic procedures, endoscopic procedures and thoracoscopic procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization.)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

Optional Format 1-

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030380